## REMARKS

The Examiner is thanked for the thoroughness of the search and examination.

Claims 1-46 are in the application as filed.

The Examiner rejects claims 1-46 under 35 U.S.C. 102(e) as anticipated by Pomatto et al (6,572,572).

Applicant submits herewith a declaration by Jeanne Hertz f.k.a. Jeanne Pomatto who is a co-inventor in the present application and is also a co-inventor of Pomatto et al. The Pomatto et al reference constitutes prior art only under 35 USC 102(e). The declaration submitted herewith shows that any invention disclosed but not claimed in Pomatto et al was derived from the inventor of this application and is thus not an invention "by another" as required under 35 USC 102(e).

The declaration submitted herewith removes Pomatto et al. as a prior art reference. Since Pomatto et al. is the primary reference relied on by the Examiner, the rejection of all claims has been traversed.

In the event that the Examiner disagrees that the attached declaration removes Pomatto et al. as a prior art reference, Applicant also provides the following substantive arguments additionally traversing the rejections.

The Examiner states that

> Pomatto, et al discloses a system comprising: a digitizer, i.e., scan controller, for substantially instantaneously capturing a three dimensional image of a head and producing first data representative of said image (See for example, col. 3, lines 37-56), and one or more computers, operable in response to said first data to automatically control manufacture of a wearable device for said head, i.e., head orthosis device (See for example, col. 4, lines 7-65).

It is respectfully submitted that Pomatto, et al does not disclose a digitizer, nor does the system of Pomatto, et al. disclose substantially instantaneously capturing a three dimensional image of a head.

Claim 1, recites:
A system comprising:

a digitizer for substantially instantaneously capturing a three dimensional image of a head and producing first data representative of said image; and

one or more computers, operable in response to said first data to automatically control manufacture of a wearable device for said head.

In paragraph [0070] it is stated:

As used herein, the term "digitizer" is utilized to identify a data capture system that produces digital data that represents the entirety of a cast or a head and which is obtained from a substantially instantaneous capture.

Pomatto et al discloses a scanner. **Pomatto et al does not disclose a "digitizer."** Since Pomatto et al does not disclose a digitizer it does not disclose a digitizer that substantially captures a three dimensional image of a head. Nor does Pomatto et al disclose a digitizer that produces first data representative of a three dimensional image.

The Examiner's attention is directed to col 3, line 57 to col. 4, line 6. This is the paragraph that bridges the two citations that the Examiner relies on. The paragraph that the Examiner omits clearly states that the **scan time is reduced to less than two seconds** by reducing the number of scan points. As pointed out in this paragraph, it is important to provide a short scan time "because it is difficult to have an infant remain immobile for more than a few seconds at a time."

The structures and methods of Pomatto et al. utilize scan technology that takes significant time to perform the scan. The scan time is not "substantially instantaneous." Pomatto et al. does not provide any enabling disclosure for a scanner that produces "substantially instantaneous" capture of a three dimensional image of a head.

Pomatto et al., recognized that it was important to scan a head in a short time, but the technology of Pomatto et al. that is disclosed can not produce a substantially instantaneous capture of a head.

Pomatto et al. does not disclose, teach or suggest **substantially instantaneously capturing** a three dimensional image of a head. **Less than two seconds as set forth in Pomatto et al. is not substantially instantaneously.**

The Merriam Webster on-line dictionary defines instantaneous as follows:

**Main Entry:** in·stan·ta·neous ☒
**Function:** *adjective*
**Pronunciation:** "in(t)-st&n-'tA-ne-&s, -nyE&s
**Etymology:** Medieval Latin *instantaneus*, from *instant-*, *instans*, n.
**1** : done, occurring, or acting without any perceptible duration of time <death was *instantaneous*>
**2** : done without any delay being purposely introduced <took *instantaneous* action to correct the abuse>
**3** : occurring or present at a particular instant <*instantaneous* velocity>

Pomatto et al. discloses a scanner system. By definition, a scanner scans. Scanning does not occur substantially instantaneously.

In contrast, the invention of the instant application describes and claims a system in which substantially instantaneous capture of a three dimensional image of a head.

The following portions of the instant specification describe and support the "substantially instantaneous capturing:"

Paragraph [0015]

a system that captures accurate three-dimensional images of infant heads without the infant being absolutely stationary or fixed in one particular orientation,

Paragraph [0051]

To provide a digitizer which utilizes a safe and noninvasive method of obtaining a 3D model of an infant's cranium, technological challenges had to be overcome that were not immediately evident during the initial stages of development. To be useful in a clinical setting, a digitizer must be fast, safe, accurate, repeatable, quiet, capture all skin tones, be impervious to motion, and not require the child to be restrained in a specific orientation. To be useful, the digitizer captures a 360° image which includes the face, top of the head, and lower occiput/neck region.

Paragraph [0054]

The infant's head is not restrained and may move in motion having pivotal, rotational and translation components. When the parent and infant are in position the system operator actuates digitizer 100 to capture and simultaneously record 18 images of the child at step 805.

Paragraph [0055]

At step 901, image capture is initiated. Simultaneously, all projectors 104 are actuated at step 903 and all cameras 102 are operated at step 904.

Paragraph [0059]

One advantage of digitizer 100 is that the image acquisition is fast enough so that motion of the infant does not present a problem for image capture, or affect the accuracy of the data acquired. If the image could not be captured 'instantaneously' it would be necessary to fixture or restrain the child in one position in order to ensure there would be no motion artifacts in the data.

Paragraph [0060]

Capture of all 18 images (12 shape, 6 texture) is accomplished through utilization of an interface 103 in FIG. 1 that functions single frame grabber circuit board. At image capture time processor 105 generates a signal via interface 103 that is sent out to all cameras 102 to simultaneously record the digital images for processing. Each camera 102 records a digital image at a speed of 1/125$^{th}$ of a second (0.008 seconds). This nearly instantaneous capture has allowed us to capture digitized images of infants in motion

Paragraph [0064]

The three-dimensional images are stored in memory 111 of digitizer 100 as shown in FIG.1. A sequence of three-dimensional images may be captured and stored in memory 111 for later playback. The three-dimensional images may be sequentially displayed to produce a three-dimensional movie of the infant or object in motion.

The present invention is a significant technological advance over the system of Pomatto et al. The present invention is not shown, taught or made obvious over Pomatto et al. Claim 1 is not anticipated, shown, taught or made obvious by Pomatto et al.

Claims 2-23 depend from claim 1. For the same reason that claim 1 is not shown, taught or made obvious by Pomatto et al, claims 2-23 are not shown, taught or made obvious by Pomatto et al.

With respect to claims 24-46, the Examiner utilizes an abbreviated style to set forth the rejections of the remaining claims.

Claim 24 recites:

A method comprising:

utilizing a digitizer to substantially instantaneously capturing a three dimensional image of a head and to produce first data representative of said image; and

providing one or more computers operable in response to said first data to automatically control manufacture of a wearable device for said head.

As set out with respect to claim 1, Pomatto et al does not disclose a digitizer or utilizing a digitizer; Pomatto et al does not disclose utilizing a digitizer to substantially instantaneously capturing a three dimensional image. In addition, Pomatto et al does not teach utilizing a digitizer to produce first data representative of the three dimensional image of a head.

Accordingly, for the same reasons that claim 1 is not anticipated, shown, taught or made obvious by Pomatto et al, claim 24 is not anticipated, shown, taught or made obvious by Pomatto et al.

Claims 25-46 depend from claim 24, and for the same reasons that claim 24 is not anticipated, shown, taught or made obvious by Pomatto et al, claims 24-46 are not anticipated, shown, taught or made obvious by Pomatto et al.

The Examiner has cited additional patents as pertinent, but has not applied those patents to the rejection of the claims.

U.S. Patents 5,094,229 and 5,951,503 describe cranial remodeling orthosis bands. However, these patents are silent on any automated fabrication of such devices.

U.S. Patent 6,340,353 is the parent of Pomatto et al, and does not add any additional bases for the Examiner's rejection.

U.S. Patent 6,423,019 is directed to a cranial remodeling orthosis that is not customized for each patient, but relies upon a bladder to conform to a head.

U.S. Patent 6,536,058 is directed to a pediatric headrest and is unrelated to fabrication of cranial remodeling orthosis devices.

U. S. Patent 6,957,961 is directed to a manikin and is unrelated to the present invention.

In view of the foregoing amendment and remarks, it is believed that the application is now in condition for allowance. Reexamination and reconsideration are requested. It is also requested that an early notice of allowance be issued ant that this application be passed to issue.

In the event that there are any additional issues with respect to the present application, the Examiner is invited to call the undersigned at (602) 463-2010.

Respectfully submitted,
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CERTIFICATE OF TRANSMISSION

I hereby certify that this document is being transmitted by facsimile on August 16, 2006 to the Commissioner for Patents, Alexandria, VA 22313-1450.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

/Donald J Lenkszus/

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